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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,281	10/13/2000	Hyun Kim	GI 5387	9127

7590 04/01/2004

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER  
1300 I STREET N.W.  
WASHINGTON, DC 20005-3315

EXAMINER
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WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/687,281	<b>Applicant(s)</b> KIM ET AL.	
	<b>Examiner</b> Jon P Weber, Ph.D.	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11-13 and 15 is/are rejected.
- 7) ☐ Claim(s) 14 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 January 2004 has been entered. Claims 1-7 and 11-16 have now been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 103***

Claims 1-5, 7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974) in view of Pheulpin (US 3,955,719), Langen et al. (US 4,784,055) and Phillips et al. (US 4,758,233).

Claims 6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. (US 5,939,974) in view of Wozney et al. (US 6,187,742) in further in view of Pheulpin (US 3,955,719), Langen et al. (US 4,784,055) and Phillips et al. (US 4,758,233).

Pheulpin (US 3,955,719) discloses a device and methods for injecting pastes of dental products into cavities (abstract), albeit not through the skin.

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Langen et al. (US 4,784,055) discloses a device and methods for injecting compositions having paste-like consistency through needles into meat. If the surface of the meat is considered its "skin", this method and device would clearly suffice to make such an injection.

Phillips et al. (US 4,758,233) disclose a device and methods to inject a medicament in the form of a cream or paste into an animal (column 1, lines 4-8). This clearly implies injecting at least through the skin.

It is still argued that the paste of Valentini et al. (US 5,939,974) cannot be injected, let alone through the skin as now required.

Newly cited Pheulpin (US 3,955,719), Langen et al. (US 4,784,055) and Phillips et al. (US 4,758,233) are provided to rebut the argument that pastes are not injectable or through the skin, the Kim Declaration notwithstanding. In the presence of demonstrated facts, the opinion of Kim is not probative.

It is noted that Wozney et al. (US 6,187,742) disclose BMP-12, *inter alia*, as now required by claim 15.

### ***Allowable Subject Matter***

Claims 14 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Claims 14 and 16 now require that the hyaluronic acid ester is Hyaff11p65. This ester does not appear to have been known in the art prior to the instant disclosure, see Campoccia et al. (1998)

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and Radice et al. (US 6,699,471), and was not disclosed in a publication until WO 03/099992.

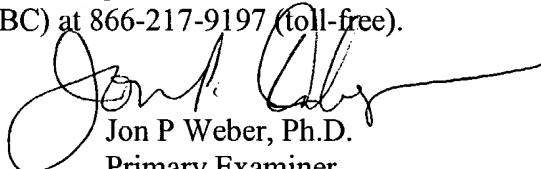
Given that the instant disclosure provides evidence of advantage of this ester over other known Hyaff11 esters disclosed in Valentini, a rejection as obvious under 103 would not be sustainable and will not be made. While della Valle et al. (US 4,581,521) teach methods of preparing various full and partial hyaluronic acid esters including benzyl used in Hyaff11, they do not explicitly disclose or reasonably suggest this particular ester or its advantages as instantly disclosed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 571-272-0925. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
29 March 2004